510(K) SUMMARY
Agfa Digital Radiography (DR) Systems with DR 400

Common Name: Solid State X-Ray Imager (Flat Panel/Digital Imager)
Classification Name: Stationary X-Ray System
Regulatory Classification: 21 CFR 892.1680
Product Code: MQB
Proprietary Name: DR 400
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Koen Vervoort, Prepared: May 7, 2014
Telephone: +32-34444-7368

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's DR 400, a solid state x-ray imaging device. It is substantially equivalent to systems with Agfa's DX-D Imaging Package (K122736) and Sedecal USA's Optima URS (K012546).

B. DEVICE DESCRIPTION

Agfa's DR 400 is a solid state x-ray system, a direct radiography (DR) system (product code MQB) intended to capture images of the human body. It is a combination of Agfa's NX workstation and one or more flat-panel detectors or photo-stimulable imaging plates and a separate digitizer.

This submission is to add the DR 400 to Agfa's direct radiology portfolio. Agfa currently markets Sedecal USA's predicate device, Optima URS (K012546) as the DX-D 400.

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is physically and electronically identical to the predicate K122736 with the exception that it now offers the CR configuration option. It uses the same workstation and the same scintillator-photodetector flat panel detectors to capture and digitize the image; however, it can also process images using photo-stimulable imaging plates.

Direct radiography systems differ from computed radiography (CR) systems in that they use scintillator-photodetector flat-panel detectors to capture the x-ray image directly instead of plates coated with photo-stimulable phosphors and a laser digitizer. Both DR and CR systems are used in place of traditional film-screen systems.

The optional image processing allows users to conveniently select image processing settings for different patient sizes and examinations. The image processing algorithms in the new device are identical to those used in the predicate (K122736).

Laboratory data and image quality evaluations conducted with independent radiologists confirm that performance is equivalent to the predicates.

C. INTENDED USE

The DR 400 system is a GenRad X-ray imaging system used in hospitals, clinics and medical practices by physicists, radiographers and radiologists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adult and pediatric patients. Applications can be performed with the patient in the sitting, standing or lying position.

Agfa's DR 400 is not indicated for use in mammography.

Intended use has not changed as a result of any labeling modification(s).

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's DR 400 has an Indications For Use statement virtually identical the predicate device (K012546) and predicate device (K122736). Intended uses are the same. The devices have the same technological characteristics.

The DR 400 indications for use is equivalent to the predicate (K122736) but includes the delineation of anatomical areas and patient positions for the imaging applications. Both the DR 400 and predicate device (K122736) include the statement that the device is not indicated for mammography, but are indicated for pediatric and neonatal patient populations. Both the DR 400 and the predicate device (K012546) indications for use statements delineate anatomical areas, patient positions for the imaging applications, and pediatric patient populations. Differences in devices do not alter the intended diagnostic effect.

The new device and the Agfa predicate device (K122736) are solid state imaging devices, Product Code MQB. Agfa's DR 400 is substantially equivalent to both predicate devices (K122736 and K012546) in that it uses precisely the same technology to capture and transmit images.

Agfa currently markets Sedecal USA's predicate device, Optima URS (K012546) as the DX-D 400 which has been reviewed and cleared by the FDA.

The difference of the device is in the addition of the CR cassettes and image plates. There are no changes to the intended use/indications of the device. The DR 400 uses the same NX workstation and the same detectors as the DX-D Image Package predicate (K122736).

Performance data including laboratory image quality measurements and image comparison studies by independent radiologists are adequate to ensure equivalence.

PRODUCT COMPARISON TABLE			
	DR 400 (New Device)	**AGFA DX-D Imaging Package (PREDICATE-K122736)**	**Sedecal Optima URS (PREDICATE-K012546)**
Communications	Same as predicates	DICOM	DICOM
Flat Panel or Image Plate	Same as predicates	Flat Panel Detector	Flat Panel Detector
Detector Material	Same as predicates	Gadolinium Oxysulfide (GOS) or Cesium Iodide (CsI) scintillator	Cesium Iodide (CsI) scintillator
Detector Sizes	Same as K122736	17x17 in. 14x17 in.	17x17 in.
Active Matrix (14x17 in.)	Same as K122736	2560 x 3072	3320 x 3408
Pixel size	Same as K122736	139 µm	125 µm
Dynamic Range	Same as K122736	14 bit	12 bit
Maximum Image Acquisitions/hr.	Same as K122736	150	100 - 180
Power Supply	Same as predicates	50-60 Hz 100-240V auto ranging	50-60 Hz 100-240V auto ranging
Operator Workstation	Same as K122736	Agfa NX	Touch Panel LCD
Image processing	Same as K122736	MUSICA^2	Standard PC Software
Operating system	Same as predicates	Windows 7	Windows 7
Display System	Same as K122736	Separately cleared medical display (K051901)	Standard PC display or separately cleared medical display

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's DR 400 is a solid state x-ray system, a direct radiography (DR) system (product code MQB) intended to capture images of the human body. It is a combination of Agfa's NX workstation and one or more flat-panel detectors or photo-stimulable imaging plates and a separate digitizer. Therefore, the DR 400 has two main configurations:

- DR configuation with x-ray exposure parameter control on the NX workstation using flat-panel detectors.
- CR configuration with x-ray exposure parameter control on the NX workstation using photo-stimulable imaging plates and a digitizer.

Both configurations use the NX workstation to process data utilizing Agfa's MUSICA^2 image processing software, which includes optional image processing algorithms for adult, pediatric and neonatal images that were previously cleared for use in Agfa's DX-D Imaging Package (K122736). The acronym MUSICA stands for **Mu**lti-**S**tage-**I**mage-**C**ontrast-**A**mplification.

MUSICA^2 acts on the acquired images to preferentially enhance the diagnostically relevant, moderate and subtle contrasts.

Principles of operation and technological characteristics of the new and predicate devices are the same. The new device is physically and electronically identical to the predicate K122736 with the exception that it now offers the CR confonfiguration option. It uses the same workstation and the same scintillator-photodetector flat panel detectors to capture and digitize the image; however, it can also process images using photo-stimulable imaging plates. There are no differences between the device and the predicates (K122736 & K012546) that impact safety and effectiveness.

F. TESTING

Laboratory testing and software testing (for a moderate level of concern device) using equivalent test protocols as used for the cleared detectors and imaging plates was evaluated by qualified individuals employed by the sponsor to demonstrate that adequate design controls (according to 21 CFR 820.30) were in place.

Image quality measurement data, performance data, and usability data has been provided.

In-hospital image quality comparisons have been conducted with qualified independent radiologists as well. Sample images have been provided in **Exhibit 7**.

Performance of the complete system has been validated and the data is provided in **Exhibit 6**.

Usability of the complete system has been validated and the data is provided in **Exhibits 5-9 to 5-13**.

The product, manufacturing and development processes conform to product safety and medical imaging standards including:

G. PRODUCT STANDARDS

- ACR/NEMA PS3.1-3.20: 2011 Digital Imaging and Communications in Medicine (DICOM).
- IEC 60601-1: 2012 Medical Electrical Equipment: General Requirements for Safety and Essential Performance.
- IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.
- IEC 60601-1-3: 2008 Medical Electrical Equipment - Part 1-3: General Requirements for Safety and Essential Performance - Collateral Standard: Radiation Protection in Diagnostic X-Ray Equipment
- IEC 60601-2-54: 2009 Medical Electrical Equipment – Part 2-54: Particular Requirements for the Basic Safety and Essential Performance of X-Ray Equipment for Radiography and Radioscopy.

QUALITY MANAGEMENT STANDARDS

- ISO 14971:2007 Application of Risk Management to Medical Devices
- ISO 13485:2003 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

H. RISK ASSESSMENT AND MANAGEMENT SUMMARY

During the final risk analysis meeting, the risk management team concluded that the medical risk is no greater than with conventional x-ray film previously released to the field.

For the DR 400 there are a total of 41 risks in the broadly acceptable region and three risks in the ALARP region. Zero risks were identified in the Not Acceptable Region. Therefore the device is assumed to be safe, the benefits of the device are assumed to outweigh the residual risk (**Exhibit 1-2**, page 2).

There are no residual risks for the released NX software versions NX8800 (NX Ikonos) in the ALARP region after mitigation. Only two risks were identified in the Broadly Acceptable Region. Therefore the device is assumed to be safe, the benefits of the device are assumed to outweigh the residual risk (**Exhibit 1-3**, page 4).

The term "Level of Concern" means the level of risk that the software device is determined to be if the software were to fail. The Level of Concern for the device has been determined to be moderate.

Refer to **Section 16 Software**, for more information regarding risk management.

I. CONCLUSIONS

Agfa's DR 400 has an Indications For Use statement virtually identical the predicate device (K012546) and predicate device (K122736). Intended uses are substantially equivalent. The devices have the same technological characteristics.

The DR 400 indications for use is equivalent to the predicate (K122736) but includes the delineation of anatomical areas and patient positions for the imaging applications. Both the DR 400 and predicate device (K122736) include the statement that the device is not indicated for mammography, but are indicated for pediatric and neonatal patient populations. Both the DR 400 and the predicate device (K012546) indications for use statements delineate anatomical areas, patient positions for the imaging applications, and pediatric patient populations.

The difference of the device is in the addition of the CR cassettes and image plates. There are no changes to the intended use/indications of the device. The DR 400 uses the same NX workstation and the same detectors as the DX-D Image Package predicate (K122736).

Differences in devices do not alter the intended diagnostic effect. Descriptive characteristics and performance data are adequate to ensure equivalence.

Agfa's DR 400 is substantially equivalent to predicates (K122736 and K012546) in that they use the same technology to capture and transmit images and use 100-240V 50/60 Hz power supply.

Agfa currently markets Sedecal USA's predicate device, Optima URS (K012546) as the DX-D 400 which has been reviewed and cleared by the FDA.

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 6, 2014

Agfa HealthCare N.V.
% Ms. ShaeAnn Cavanagh
Regulatory Affairs Specialist NA
10 South Academy Street
GREENVILLE SC 29601

Re: K141192
Trade/Device Name: DR 400
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: May 7, 2014
Received: May 8, 2014

Dear Ms. Cavanagh:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141192

Device Name

DR 400

Indications for Use *(Describe)*

The DR 400 system is a GenRad X-ray imaging system used in hospitals, clinics and medical practices by physicists, radiographers and radiologists to make, process and view static X-ray radiographic images of the skeleton (including skull, spinal column and extremities), chest, abdomen and other body parts on adult and pediatric patients. Applications can be performed with the patient in the sitting, standing or lying position.

Agfa's DR 400 is not indicated for use in mammography.

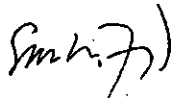
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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